

## **REMARKS**

Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request entry of the amendment and reconsideration of the claims.

Claims 1, 16, and 20 have been amended. Claims 2, 6-15, 17, 23, and 26-28 were previously canceled. Thus, claims 1, 3-5, 16, 18-22 and 24-25 are pending in the application.

Claims 1, 3, 4, 5, 16, 18-22 and 24-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Easley (US 6599271) in view of Maaskamp (US 6149633) in further view of Ureche et al (US 51677620). Applicant respectfully traverses these rejections.

To understand why Applicant's claimed inventions are not obvious in view of the cited art, it is important to understand the problem that is sought to be solved by the prior art and by Applicant's claimed inventions. The basic problem to be solved is that when an aspiration line of a phacoemulsification system is plugged by debris being suctioned away from the phacoemulsification tip during cataract removal, a large vacuum builds up between the aspiration source and the plug. The typical location of such a plug is within the phacoemulsification handpiece, which is typically connected to the aspiration tube by a length of flexible elastic tubing. The vacuum resulting from the plug is typically sufficient to cause the flexible elastic tubing to collapse. When the plug eventually dislodges, vacuum behind the plug causes a rapid decrease in the pressure at the tip of the phacoemulsification handpiece, which, because it is disposed within a patient's eye during the procedure, results in collapse of the cornea of the eye due to the decreased pressure. Those skilled in art know that such a collapse can result in significant damage to the endothelium of the cornea, leading to increased post-surgical complications.

Easley acknowledges this problem, stating:

An additional cause for pressure change is the elastic nature of the tubing connecting the eye to the vacuum source. The diameter of the tubing changes, based on the pressure difference between the inside of the tubing and atmospheric pressure. That is to say, the tubing becomes smaller as vacuum increases. These diameter changes cause the tubing to store energy, damping pressure changes in the tubing. . . When the occlusion breaks suddenly, the energy stored in the aspirating tubing causes a surge of fluid to

flow, as the tubing returns to the size it was before the occlusion.  
US 6,599,271, Col. 2, ll. 15-29.

Thus, Easely teaches that use of flexible tubing is detrimental to flow control, and instead discloses using a variable orifice device attached to the phacoemulsification handpiece in such a manner that all flexible tubing is eliminated between the variable orifice and the handle wherein increases of vacuum cause only insignificant changes in volume between an ultrasound needle tip and the variable orifice. *See* Easely, Figure 2 and Col. 8, ll. 1-33.

Maaskamp does not even address the same problem addressed by either Easely or Applicant's claimed inventions. Instead, Maaskamp only discloses a system for balancing the flow between two branches of a fluid circuit. In Maaskamp's case, suction is applied to an intra-cavity line and to a line configured to capture fluid overflowing from the body cavity. Maaskamp adjusts the flow impedances of the lines to equalize pressure within the two drain lines. Maaskamp is not concerned with collapse of the body cavity, and certainly there is no mention of preventing corneal collapse. Moreover, there is no disclosure concerning the linearity or non-linearity of the flow through the lines. Those skilled in the art reading Maaskamp would not expect such a discussion, since such matters are irrelevant to the problem being solved by Maaskamp.

Ureche also does not help the combination of art, since while Ureche does acknowledge the problem, Ureche discloses only using a variable flow resistance element that changes its flow resistance as a function of the amount of vacuum applied to it by deforming in response to the vacuum. *See*, Ureche, col. 5, lines 2-42 and col. 6, lines 27-59 and the accompanying figures. This deformation is exactly the problem that Easely was trying to eliminate, as discussed above. Accordingly, Applicant respectfully submits that the combination of Ureche with Easely and Maaskamp, given Easely's teaching away from the Ureche's disclosure, would not teach Applicant's claimed invention to one skilled in the art.

Even assuming that the Examiner is correct that one skilled in the art would incorporate the tubing sizes disclosed by Maaskamp, Easely's device still requires that there be no elastic tubing between his variable orifice device and the phacoemulsification handpiece. Thus, combining Maaskamp and Easely would also not teach Applicant's claimed invention to one skilled in the art.

What would be apparent to those skilled in the art, especially in view of Easely's disclosure of the problems associated with the inclusion of deformable tubing between a restrictor device and the handpiece, is the unexpected result of using Applicant's claimed inventions coupled to a proximal end of an aspiration line to prevent collapse of an eye during cataract removal. As claimed in amended claims 1, 16 and 20, Applicant's claimed flow restrictor having a fixed orifice is coupled to a proximal end of the aspiration tube, and provides a non-linear flow relations that limits surges in fluid pressure from exceeding a selected maximal flow rate and thus prevents collapse of the eye. None of the prior art, taken alone or in combination, teach or even suggest such a novel combination of features, elements and functions as claimed by Applicant.

For these reasons, Applicant believes that the claimed inventions are not obvious in view of the art cited by the Examiner, and no one skilled in the art, even combining the art as suggested by the Examiner, would obtain Applicant's claimed inventions. Accordingly, Applicant respectfully submits that claims 1, 3-5, 16, 18-22, 24 and 25 are patentable over the cited art, and requests that the rejections be withdrawn and the claims allowed.

## **CONCLUSION**

Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request entry of the amendment and reconsideration of the claims in view of the remarks presented. In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Should the Examiner have any questions concerning the above amendments and arguments, or any suggestions for further amending the claims to obtain allowance, Applicants request that the Examiner contact Applicants' attorney, John Fitzgerald, at 310-242-2667.

The Commissioner is authorized to credit any overpayment or charge any additional fees in this matter to our Deposit Account No. 06-2425.

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Respectfully submitted,

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